

**Remarks**

Claims 3, 13, and 14 are amended herein; new claims 15 and 16 are added. The pending claims are claims 3, 5, and 10-16.

The amendments to claims 3, 13, and 14 are supported throughout the specification, e.g., by originally filed claim 3. Claims 15 and 16 are supported, e.g., by originally filed claim 3 and at page 2, lines 7-8.

The amendments to the paragraph beginning on page 2, line 6, add reference to the protein and nucleotide EpoR sequences reported by Winkelmann et al. and Jones et al., cited specifically at page 2, lines 7-8. Accordingly, the addition of the sequences does not add new matter. Likewise, addition of the reference to SEQ ID NO:4 in the paragraph beginning at page 14, line 10 is supported by the citation of the Winkelmann et al. cDNA sequence at page 2, line 8.

SEQ ID NO:5 is the human EpoR polypeptide encoded by the cDNA reported by Winkelmann et al., SEQ ID NO:4, and is supported at page 2, line 8 of the specification. SEQ ID NO:6 is the human EpoR cDNA reported by Jones et al., supported at page 2, lines 7-8 of the originally filed specification. SEQ ID NO:7 is the EpoR polypeptide encoded by SEQ ID NO:6, the cDNA reported by Jones et al. Accordingly, SEQ ID NOS:5-7 are not new matter.

**The Rejection of the Claims Under 35 U.S.C. § 101**

Claims 3 and 13 were rejected as directed to non-statutory subject matter. This rejection is respectfully traversed.

The Examiner stated that the recitation of “A polypeptide . . .” covered naturally occurring polypeptides. The claims have been amended to recite “An isolated polypeptide . . .” instead of “A polypeptide . . .”, obviating this rejection.

In view of the amendments and remarks herein, it is requested that the Examiner withdraw the rejection of claims 3 and 13 as directed to non-statutory subject matter under 35 U.S.C. § 101.

*The Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph*

Claims 3, 5, and 11-14 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

The Examiner stated that the description of one polypeptide (SEQ ID NO:5) is not adequate written description of a genus of functionally equivalent polypeptides. The Examiner further stated that the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and that the compound itself is required. First, it is not correct under the law that description of one polypeptide cannot provide adequate written description of a genus. Second, Applicant has described the structure of two members of the genus, SEQ ID NO:5 and SEQ ID NO:7.

Applicant is not required, as the Examiner states or implies, to provide the exact chemical structure of all species of a claimed genus of polypeptides or other chemical compounds. The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement (Fed. Reg. Vol. 66, No. 4, January 5, 2001, page 1099-1111) (Written Description Examination Guidelines) states:

Whether the specification shows the applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. (page 1106, quoting *Regents of the Univ. California v. Eli Lilly*, 119 F.3d 1559, 1566 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998)).

The present application more than meets this standard. (1) The level of skill in the biological arts is high. See *In re Wands*, 8 U.S.P.Q.2d 1400, 1406 (Fed. Cir. 1988)

(“There was a high level of skill in the [hybridoma] art.”) and *Enzo Biochem Inc. v. Calgene Inc.*, 52 U.S.P.Q.2d 1129, 1136 (Fed. Cir. 1999) (“a person of ordinary skill in the [biochemical] art would be a junior faculty member . . . or a postdoctoral student with several years of experience.”). (2) The applicant has provided not just a partial structure, but the exact structures, SEQ ID NO:5 and SEQ ID NO:7, of not one but two members of the genus of human erythropoietin receptor polypeptides, possibly the only members of the genus. (3) The applicant has disclosed the function of the receptor polypeptide and of the extracellular domain – binding erythropoietin – and disclosed that the function is linked to the detailed structures provided.

“The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species . . . .” *Id* at page 1106. “A ‘representative number of species’ means that the species . . . described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the species. On the other hand, there may be situation where one species adequately supports a genus. What constitutes a representative number is an inverse function of the skill and knowledge in the art.” *Id* at 1106.

It is likely there is only two isoforms of human erythropoietin receptor polypeptide and the applicant has disclosed the exact structure of the entire genus. But humans are not all genetically identical, and there is a reasonable possibility that one or more other isoforms of the erythropoietin receptor exist. Any other functional isoforms would almost certainly differ little from SEQ ID NOS:5 and 7. Thus, any other isoforms would be immediately recognized as isoforms of the erythropoietin receptor, and the boundaries of the genus are clear. Likewise, an isoform of the full-length erythropoietin receptor DNA that differs slightly from SEQ ID NOS:4 or 6 may exist in nature in the diversity of genetics among individual humans. But such an isoform would be easily recognized as an erythropoietin receptor DNA. Thus the boundaries of the genus are clear.

Description of the exact structure of two polypeptides (SEQ ID NOS:5 and 7) is clearly adequate description of such a narrow genus as human erythropoietin receptor

protein, which may only have two species. Even if the genus has more than two species the species are extraordinarily closely related.

“It is manifestly impracticable for an applicant who discloses a generic invention to give an example of every species falling within it . . .” *In re Surrey*, 151 U.S.P.Q. 724 (C.C.P.A. 1966). In this case, however, it is very possible the applicant has given an example of every species falling within the genus. Likewise, the applicant may have given an example of every species of human erythropoietin receptor DNA.

In view of the remarks herein, it is requested that the Examiner withdraw the rejection of Claims 3, 5, and 11-14 under the written description requirement of 35 U.S.C. § 112, first paragraph.

*The Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph*

Claims 3, 5, and 11-14 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. This rejection is respectfully traversed.

The Examiner stated that the phrase “consisting essentially of” in claims 3 and 11 rendered the claims indefinite. Claim 3 recites an isolated polypeptide consisting essentially of amino acid 25 to amino acid 250 of full length human erythropoietin receptor protein, said polypeptide having a specific affinity for human erythropoietin, wherein said polypeptide has a molecular weight of 29 kDa.

The phrase “consisting essentially of” has well established use in patent claims and, contrary to what the Examiner’s rejection suggests, the phrase does not *per se* render claims indefinite. The transition “consisting essentially of” renders a claim open for the inclusion of only unspecified ingredients that do not “materially affect the basic and novel characteristics of the claimed composition.”<sup>1</sup> Claim 3 recites those material and novel characteristics of the polypeptide that unspecified additional components may not alter – having a specific affinity for human erythropoietin and having a molecular weight of 29 kDa. Thus, it is respectfully submitted that the metes and bounds of claim 3 and

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<sup>1</sup> *Dow Chem. Co. v. American Cyanamid Co.*, 615 F. Supp 471,484, 229 U.S.P.Q. 171, 180 (E.D. La. 1985), *aff’d* 816 F.2d 617, 2 U.S.P.Q.2d 1350 (Fed. Cir. 1987); *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984); *PPG Indus. v. Guardian Indus. Corp.*, 156 F3d 1351, 1355, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998).

claims 5 and 10-12, which depend from claim 3, are definite under 35 U.S.C. § 112, second paragraph.

The Examiner stated that claims 13 and 14 are indefinite because claim 13 recites "... a polypeptide consisting of a *free* human erythropoietin receptor domain . . . ." The word "free" has been deleted from claim 13, obviating this basis for the rejection.

In view of the remarks herein, it is requested that the Examiner withdraw the rejection of claims 3, 5, and 11-14 as indefinite under 35 U.S.C. § 112, second paragraph.

*The Rejection of the Claims Under 35 U.S.C. § 102(b)*

Claims 3, 5, and 11-14 were rejected under 35 U.S.C. § 102(b) as being anticipated by Jones et al. (*Blood* 76:31-35 (1990)). This rejection is respectfully traversed.

Jones et al. discloses an isolated nucleic acid encoding the full-length human erythropoietin receptor polypeptide having 508 amino acid residues (Figure 1A and B). The protein is disclosed to include a putative signal sequence cleavage site between residues 24 and 25, a putative extracellular domain of residues 25 to 250, a transmembrane domain of residues 251 to 272, and a C-terminal domain of residues 273 to 508 (Figures 1A and B). Jones et al. discloses expressing the full-length human Epo receptor polypeptide to produce a protein of about 66 kDa (page 33, column 2). Jones et al. discloses that a pre-B-lymphocyte cell line, Ba/F3, was transfected with a linearized plasmid expressing the Epo receptor. Jones et al. discloses that the transformed cells grew in Epo-containing medium, but mock transformed cells did not grow (pages 33-34). This suggests that the full-length Epo receptor was expressed from the linearized plasmid.

Claims 3, 5, 11, and 12 recite an isolated polypeptide consisting essentially of amino acid 25 to amino acid 250 of full length human erythropoietin receptor protein, said polypeptide having a specific affinity for human erythropoietin, wherein said polypeptide has a molecular weight of 29 kDa.

Jones et al. discloses expressing a full-length Epo receptor, having 518 amino acids, a molecular mass of about 66 kDa, and having, in addition to the extracellular domain of residues 25-250, a carboxyl terminal domain, an N-terminal signal sequence,

and a transmembrane domain. Claims 3, 5, 11, and 12, in contrast, recite an isolated polypeptide consisting essentially of residues 25-250 and having a molecular mass of 29 kDa. Thus, Jones et al. does not anticipate claims 3, 5, 11, and 12. The claims recite a polypeptide of 29 kDa and Jones et al. discloses a polypeptide of 66 kDa.

Claims 13 and 14 recite an isolated polypeptide consisting of a human erythropoietin receptor extracellular domain, wherein the extracellular domain is expressed from a region of a full-length human erythropoietin receptor DNA defined on the 5' end by a forward primer SEQ ID 1 [which begins with nucleotides encoding amino acid residue 25] and defined at the 3' end by a reverse primer SEQ ID 2 [which begins with nucleotides complementary to the nucleotides encoding amino acid residue 250].

Jones et al. discloses expression of a full-length Epo receptor polypeptide containing not only the extracellular domain of Epo receptor (residues 25-250), but also a carboxyl terminal domain, an N-terminal signal sequence, and a transmembrane domain. Thus, Jones et al. does not anticipate claims 13 and 14 reciting a polypeptide consisting of a Epo receptor extracellular domain and expressed from a region of a full-length Epo receptor DNA.

In view of the remarks herein, it is requested that the Examiner withdraw the rejection of claims 3, 5, and 11-14 under 35 U.S.C. § 102(b) as being anticipated by Jones et al. (*Blood* 76:31-35 (1990)).

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (651-207-8270) to facilitate prosecution of this application.

Respectfully submitted,

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